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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/895,040 | 06/29/2001 | Mark E. Shannon | AEOMICA-011 | 7478 |

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| EXAMINER | |
|---|---|
| GOLDBERG, JEANINE ANNE | |
| ART UNIT | PAPER NUMBER |
| 1634 | |

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/895,040 | SHANNON ET AL. | |
| | Examiner | Art Unit | |
| | Jeanine A Goldberg | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *57-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. This action is in response to the papers filed February 11, 2003. Currently, claims 57-75 are pending. Claims 1-56 have been cancelled.

2. Any rejection or objection not herein reiterated is hereby withdrawn in view of the amendments to the claims and applicant's remarks.

3. This action is FINAL.

### *Priority*

4. This application claims priority to several PCT applications in addition to CIP of 09/864,761, filed May 23, 2001. The priority documents contain no description of SEQ ID NO: 1, 2, 3, 4, 6 or 7. Therefore, the instant claims enjoy the benefit of June 29, 2001, the instant filing date.

### *New Matter*

5. Claims 58-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "at least 99% identical in sequence to SEQ ID NO: 3" and "at least 95% identical in sequence to SEQ ID NO: 3" are included. The amendment asserts that no new matter has been entered. However, the specification does not describe or discuss to "at least 99% identical in sequence to SEQ ID NO: 3"

and "at least 95% identical in sequence to SEQ ID NO: 3". Instead the specification describes nucleic acids which are not only identical in sequence to those described, but also nucleic acids about 95% and 99% identical (page 19, lines 21-35). This description does not support to "at least 99% identical in sequence to SEQ ID NO: 3" and "at least 95% identical in sequence to SEQ ID NO: 3". The specification does not appear to contemplate percent identity with the polypeptide which encodes a nucleic acid. The concept of "at least 99% identical in sequence to SEQ ID NO: 3" and "at least 95% identical in sequence to SEQ ID NO: 3" does not appear to be part of the originally filed invention. Therefore, to "at least 99% identical in sequence to SEQ ID NO: 3" and "at least 95% identical in sequence to SEQ ID NO: 3" constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 57-75 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to isolated nucleic acids comprising SEQ ID NO: 1 or 2; a degenerate variant of SEQ ID NO: 2; a nucleic acid which encodes SEQ ID NO: 3 and sequences which are 95 or 99% identical to the recited sequences.

The specification teaches that SEQ ID NO: 1 is the full length cDNA with untranslated regions. The specification teaches SEQ ID NO: 2 is the open reading frame. The specification teaches SEQ ID NO: 3 is the full amino acid sequence. The human GRBP2 cDNA spans 3484 nucleotides and contains an open reading frame from nucleotide 21 through and including nucleotide 2081. The predicted protein is 686 amino acids with a molecular weight of 77.0 kD. The specification asserts that the reading frame appear full length because it begins with a methionine and terminates with a stop codon (page 129). The specification teaches SEQ ID NO: 4 is the 5' untranslated region and initial coding sequence. SEQ ID NO: 6 is the 5' untranslated region not in the alternative minor form disclosed prior to the instant filing date. SEQ ID NO: 7 is the amino acid sequence not found in the alternative form. The specification teaches that GRBP2 interacts with GTPase Rho. The specification asserts that levels of human GRBP2 mRNA in cells may be assessed to diagnose oncogenesis (page 124). The specification asserts that Tables 1 and 2 show significant expression of exons 2, 3, 6, 11 and 15 in kidney, adrenal, adult liver, bone marrow, brain, fetal liver, heart, hela, lung, placenta, prostate and skeletal muscle (page 128). The specification teaches that the human GRBP2 gene can be mapped to human chromosome 19q12 (page 129). In a BLAST search the GRBP1 mouse shares 46% amino acid identity and 61% amino acid identity over 583 amino acids (page 131). Additionally another mouse gene is 85% identical at the amino acid level and 91% identity over 686 amino acids (page 131). The specification provides that certain protein domains and overall structural organization are shared with mouse Grbp1 and Grbp2 (page 132). The

specification hypothesizes that the "shared structural features strongly imply that human GRBP2 and murine Grbp2 play a role similar to that of mouse Grbp1 as a putative adaptor protein that interacts with both the small GRPase Rho as well as elements of the actin cytoskeleton, with a potential role as a proto-oncogene/oncogene (page 132). The human GRBP2 contains HR1 domain, residues 38-98 of SEQ ID NO: 3 and a PDZ domain at residues 513-594 of SEQ ID NO: 3 (page 132). The specification provides the standard protocol for determining whether an association between increased GRBP2 expression is indicative of neoplasia. The specification provides that certain chromosomal regions may to locations known to be associated with diseases.

In analyzing each of the tests for establishing utility, GRBP2, SEQ ID NO: 1-3, fail to have either a specific or substantial or a well-established utility. First the specification asserts that the utility for the GRBP2 nucleic acids are for expression analysis indicative of neoplasia. The art does not support the assertion of the association between GRBP2 and neoplasia.

It is noted that the utility of the invention must have existed at the time of filing. However, the post filing date art (Saatcioglu, WO 01/72962, October 4, 2001) demonstrates that PSL22 gene and mRNA, which is over 99% identical with SEQ ID NO: 1, 2 and 3 of the instant application, is expressed in various human tissues including prostate, kidney, pancreas and colon. Saatcioglu teaches the androgen regulation of PSL22 was examined in PC3 and DU145 cells, in androgen-independent prostate cancer cell lies and in CWR22R cells. The analysis demonstrates that PSL22

is androgen regulated in LNCaP cells, where it is highly expressed, but not in androgen regulated PC2 and Du145 cell (page 62). This analysis has not demonstrated any overexpression in neoplasia generally, nor in prostate cancer because there does not appear to be any correlation between normal and cancerous cells presented.

Turning to the teachings in the specification, the asserted utility is neither specific nor substantial as a marker for prostate cancer. A substantial utility is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The asserted utility of a marker for neoplasia requires carrying out further research to reasonably confirm a "real world" use. The specification asserts that "diseases that map to the human GRBP2 chromosomal region" including oncogene liposarcoma, ichthyosis congentita III and benign familial infantile convulsions (page 139). This passage illustrates that as of the time of filing, the specification has not performed any analysis studies to determine whether GRBP2, namely SEQ ID NO: 1-4, 6-7, has altered expression and whether the altered expression is strongly correlated with any particular neoplasia in particular. The specification demonstrated the expression level of GRBP2 in numerous normal tissues including, kidney, adrenal, adult liver, bone marrow, brain, fetal liver, heart, hela, lung, placenta, prostate and skeletal muscle (page 128). Therefore, the skilled artisan would be required to perform further research to confirm the use of SEQ ID NO: 1-3 as a marker for neoplasia. There is no indication in the specification whether the marker is expressed in both normal and disease tissue or whether the over or underexpression of the nucleic acid is indicative of

a disease state. Additionally, the specification has provided no threshold or range which would indicate to the skilled artisan how to determine whether a tissue was neoplastic. There is no suggestion in the specification whether the maker is associated with all neoplastic tissue or whether the marker is specific for a specific neoplasia. Therefore, upon determining whether there is expression within a set of neoplsia, the range of expression as indicative of normal, benign or neoplastic tissue, the skilled artisan would be required to interpret these results to obtain a meaningful real world use. Each of these inquiries are required prior to the skilled artisan being able to use the claimed invention.

Additionally, the assertions in the specification which hypothesize that the "shared structural features strongly imply that human GRBP2 and murine Grbp2 play a role similar to that of mouse Grbp1 as a putative adaptor protein that interacts with both the small GRPase Rho as well as elements of the actin cytoskeleton, with a potential role as a proto-oncogene/oncogene (page 132)" do not provide evidence that the nucleic acid is either a proto-oncogene nor an oncogene. The utility of Grbp1 does not appear to be settled in the art. The specification merely asserts that the protein interacts with the small Rpase Rho and elements of the actin cytoskeleton. Neither of these functions of the protein provide a real world use for the protein. The specification nor the art has provided any general teachings of utility for proteins which interact with Rho or with PDZ domain containing proteins.

The claims have been amended to further allow for variability within the sequences of SEQ ID NO: 2 and 3 such that the claims are drawn to 95 and 99%

identity with the sequences. The specification has not provided any clear analysis of the nucleic acids structure such that the nucleic acid may be modified to 95 and 99% identity and maintain any function of the nucleic acid for "binding GTPase, Rho."

As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Therefore, since the specification fails to provide a well established or a specific and substantial utility, the claimed invention lacks utility.

**Response to Arguments**

The response traverses the rejection. The response asserts that the claimed subject matter is directed to nucleotide sequences encoding a novel protein that contains a predicted HR1 motif (page 13 of the response filed February 11, 2003). The response asserts that the HR1 motif was well known at the time the application was filed to bind specifically to a small GTPase, Rho. In support of this assertion, Applicant's filed a copy of Reid. It is noted that this reference has not been included on a 1449, therefore, will not appear on the face of any patent which may issue.
The instant application does not provide any indication that the nucleic acid in fact binds to small GTPase, Rho. The nucleic acid merely contains a HR1 motif which the response asserts is instrumental in binding the small GTPase, Rho.
When looking at Figure 1B directed to the HR1 domains, the consensus and the GRBP2 domains do not exhibit extensive similarity. The specification also indicates that

theGRBP2 protein resembles more closely an uncharacterized putative mouse gene (GenBank Accession Number BAB23615) than the GRBP1 mouse protein. Therefore, it is not clear that the assignment as binding to GTPase, Rho is predictable absent further experimentation. The skilled artisan would be required to perform additional experimentation to confirm a "real world context of use." The presence of a HR1 motif has been characterized and studied by Flynn (J. of Biol. Chemistry, Vol. 273, No. 5, pages 2698-2075, 1998) as three distinct subregions, namely a, b, c. Flynn has determined that each of these regions which are aligned in Figure 1 do not have the same binding affinity (page 2700, col. 1). Flynn teaches that "both the HR1a and HR1b GST fusion proteins bound RhoA; no bindings was observed for HR1c nor for the GST control." Flynn teaches that the greater sequence similarity between HR1a and HR1b compared with HR1c is consistent with this pattern of behavior. Therefore, the instant protein and the consensus showin the Figure 1B of the instant application demonstrate that the sequence similarity in the region is low. Therefore, absent further research to confirm the real world context of use, the instant nucleic acids lack specific or substantial utility.

Moreover, even in the event that the nucleic acid were shown to bind GTPase, Rho, this information does not provide a real world context of use. As discussed in the rejection above, one of the specific roles of G-proteins lies in cellular control which encompasses cell proliferation. It is clear from the post filing date art, that the nucleic acids are expressed in normal tissues and has not established a correlation in any specific cancer or in cancers generally. Therefore, absent further research, the ability of

the nucleic acid to bind GTPase, Rho would not constitute a specific and substantial utility.

The response also asserts that the "class of nucleotide sequences are commercial available." This argument has been reviewed but is not convincing because, as stated above the instant nucleic acid has not been demonstrated to be a GTPase binding protein. Furthermore, the commerciality of the fusion proteins may be solely directed to facilitating further research of compounds, as opposed to a patentable utility which meets the criteria of specific, substantial and credible required by the Utility Guidelines. It is noted that the examiner did not receive a copy of the documents that applicant asserted were printouts from the web page. Moreover, these references were not cited on a 1449, therefore, will not appear on the face of a patent which may eventually publish.

The claims have been amended to recite percent homology for SEQ ID NO: 2 and 3. The rejection has been modified to reflect this new limitation.

Thus for the reasons above and those already of record, the rejection is maintained.

***Claim Rejections - 35 USC § 112- Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 57-75 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The claims are broadly drawn to isolated nucleic acids comprising SEQ ID NO: 1 or 2; a degenerate variant of SEQ ID NO: 2; a nucleic acid which encodes SEQ ID NO: 3..

The specification teaches that SEQ ID NO: 1 is the full length cDNA with untranslated regions. The specification teaches SEQ ID NO: 2 is the open reading frame. The specification teaches SEQ ID NO: 3 is the full amino acid sequence. The human GRBP2 cDNA spans 3484 nucleotides and contains an open reading frame from nucleotide 21 through and including nucleotide 2081. The predicted protein is 686 amino acids with a molecular weight of 77.0 kD. The specification asserts that the reading frame appear full length because it begins with a methionine and terminates with a stop codon (page 129). The specification teaches SEQ ID NO: 4 is the 5' untranslated region and initial coding sequence. SEQ ID NO: 6 is the 5' untranslated region not in the alternative minor form disclosed prior to the instant filing date. SEQ ID NO: 7 is the amino acid sequence not found in the alternative form. The specification teaches that GRBP2 interacts with GTPase Rho. The specification asserts that levels of human GRBP2 mRNA in cells may be assessed to diagnose oncogenesis (page 124). The specification asserts that Tables 1 and 2 show significant expression of exons 2, 3, 6, 11 and 15 in kidney, adrenal, adult liver, bone marrow, brain, fetal liver,

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The post filing date art (Saatcioglu, WO 01/72962, October 4, 2001) demonstrates that PSL22 gene and mRNA, which is over 99% identical with SEQ ID NO: 1, 2 and 3 of the instant application, is expressed in various human tissues including prostate, kidney, pancreas and colon. Saatcioglu teaches the androgen regulation of PSL22 was examined in PC3 and DU145 cells, in androgen-independent

prostate cancer cell lies and in CWR22R cells. The analysis demonstrates that PSL22 is androgen regulated in LNCaP cells, where it is highly expressed, but not in androgen regulated PC2 and Du145 cell (page 62). This analysis has not demonstrated any overexpression in neoplasia generally, nor in prostate cancer because there does not appear to be any correlation between normal and cancerous cells presented.

Turning to the teachings in the specification, the skilled artisan would be unable to use the claimed nucleic acids as a marker for prostate cancer absent additional undue experimentation. While one could conduct additional experimentation to determine whether, e.g. the nucleic acids of ESQ ID NO: 1-4, 6-7 at certain levels might be associated with, e.g. certain types of neoplasia, the outcome of such research cannot be predicted, and such further research and experimentation are both unpredictable and undue. The specification asserts that "diseases that map to the human GRBP2 chromosomal region" including oncogene liposarcoma, ichthyosis congentita III and benign familial infantile convulsions (page 139). This passage illustrates that as of the time of filing, the specification has not performed any analysis studies to determine whether GRBP2, namely SEQ ID NO: 1-4, 6-7, has altered expression and whether the altered expression is strongly correlated with any particular neoplasia in particular. The specification demonstrated the expression level of GRBP2 in numerous normal tissues including, kidney, adrenal, adult liver, bone marrow, brain, fetal liver, heart, hela, lung, placenta, prostate and skeletal muscle (page 128). Therefore, the skilled artisan would be required to perform further research to confirm the use of SEQ ID NO: 1-4, 6-7 as a marker for neoplasia. There is no indication in the

specification whether the marker is expressed in both normal and disease tissue or whether the over or underexpression of the nucleic acid is indicative of a disease state. Additionally, the specification has provided no threshold or range which would indicate to the skilled artisan how to determine whether a tissue was neoplastic. There is no suggestion in the specification whether the maker is associated with all neoplastic tissue or whether the marker is specific for a specific neoplasia. Therefore, upon determining whether there is expression within a set of neoplsia, the range of expression as indicative of normal, benign or neoplastic tissue, the skilled artisan would be required to interpret these results to obtain a meaningful real world use. Each of these inquiries are required prior to the skilled artisan being able to use the claimed invention.

Additionally, the assertions in the specification which hypothesize that the "shared structural features strongly imply that human GRBP2 and murine Grbp2 play a role similar to that of mouse Grbp1 as a putative adaptor protein that interacts with both the small GRPase Rho as well as elements of the actin cytoskeleton, with a potential role as a proto-oncogene/oncogene (page 132)" do not provide evidence that the nucleic acid is either a proto-oncogene nor an oncogene. The utility of Grbp1 does not appear to be settled in the art. The specification merely asserts that the protein interacts with the small Rpase Rho and elements of the actin cytoskeleton. Neither of these functions of the protein provide a skilled artisan to make and use for the nucleic acid. The specification nor the art has provided any general teachings of utility for proteins which interact with Rho or with PDZ domain containing proteins.

The claims have been amended to further allow for variability within the sequences of SEQ ID NO: 2 and 3 such that the claims are drawn to 95 and 99% identity with the sequences. The specification has not provided any clear analysis of the nucleic acids structure such that the nucleic acid may be modified to 95 and 99% identity and maintain any function of the nucleic acid for "binding GTPase, Rho."

**Response to Arguments**

The response traverses the rejection. The response asserts that the claims display a well-established utility for the reasons advanced above. This argument has been reviewed but is not convincing for the reasons presented above. Thus for the reasons above and those already of record, the rejection is maintained.

***Claim Rejections - 35 USC § 112-Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 58-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid sequence of at least 99% or 95% identity to SEQ ID NO: 2 or a nucleotide sequence that encodes a polypeptide at least 99% or 95% identical to SEQ ID NO: 3.

The specification teaches that SEQ ID NO: 1 is the full length cDNA with untranslated regions. The specification teaches SEQ ID NO: 2 is the open reading frame. The specification teaches SEQ ID NO: 3 is the full amino acid sequence. The specification teaches SEQ ID NO: 4 is the 5' untranslated region and initial coding sequence. SEQ ID NO: 6 is the 5' untranslated region not in the alternative minor form disclosed prior to the instant filing date. SEQ ID NO: 7 is the amino acid sequence not found in the alternative form.

The claims have been amended to further allow for variability within the sequences of SEQ ID NO: 2 and 3 such that the claims are drawn to 95 and 99% identity with the sequences. The specification has not provided any clear analysis of the nucleic acids structure such that the nucleic acid may be modified to 95 and 99% identity and maintain any function of the nucleic acid for "binding GTPase, Rho." The specification has not described which amino acid changes or nucleotide changes will result in a functioning polypeptide. Therefore, there is no structure function relationship which has been described as required by the Written guidelines where a partial structure is defined. The claims also read on nucleic acid which have not been described. The claims encompass allelic variants, splice variants, homologues and related sequences, for example. Thus, the specification has not provided a representative number of species for the large genus of nucleic acids which are 99% or

95% identical to SEQ ID NO: 2 or 3. There is no description of the mutational sites that exist in nature and no description of how the structure of SEQ ID NO; 2 and 3 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present stat of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. The art, namely Flynn teaches the structure of the protein influences the function of the protein to bind Rho. Therefore, variations and mutations within the sequence may not provide adequate description of the nucleic acid. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

***Conclusion***

**8. No claims allowable.**

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
May 12, 2003

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600